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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/508, 979 05/10/00 HIGGINS

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023713 HM22/0619
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SUITE 201
BOULDER CO 80303

EXAMINER

COLLINS, C

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/508,979	HIGGINS ET AL.
	Examiner Cynthia Collins	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 May 2000.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-65,67-69 and 83-100 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-65,67-69 and 83-100 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. A foreign priority is claimed.

Information Disclosure Statement

2. Initialed and dated copies of Applicant's IDS forms 1449, Paper Nos. 6-8, are attached to the instant Office action.

Drawings

3. The drawings are objected to by the Draftsperson as informal for the reasons indicated on Form PTO 948.

Claim Objections

4. Claim 100 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 100 is dependent on itself and therefore fails to further limit the subject matter of a previous claim.

Claim Rejections - 35 USC § 112 and 35 USC § 101

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3-4, 37, 42, 47, 52, 68, 83-89, 96, and 99 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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7. Claim 1 is indefinite because the use of the alternative "and/or" is confusing. It is confusing in that it suggests an alternative in which the modified metabolites do consist of only the sulfurous protein content of a seed.

8. Claims 1, 42, 47, and 52 are indefinite because the use of the phrase "at least" to modify "comprising" is redundant.

9. Claims 3 and 68 are indefinite because the transitional phrase preceding a Markush group should be "consisting of" rather than "comprising".

10. Claims 4 and 37 are indefinite because they are unduly alternative.

11. Claim 42 is indefinite because it is unclear whether the phrase "modified composition of any amino acid" refers to the composition of any amino acid or to the concentration of any amino acid.

12. Claims 83-85 provide for the use of a transformed plant, progeny, and plant part, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

13. Claims 83-85 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

14. Claims 86-87 recite the limitation "storage organ". There is insufficient antecedent basis in claims 21, 38, 42, 47, 52, or 58 for this limitation in claims 86-87.

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15. Regarding claim 88, the phrase "total content of the seed" renders the claim indefinite because it is unclear what constitutes the "total content" of the seed.

16. Regarding claims 88 and 89, the phrase "does not only increase the sulfurous content of the seed" renders the claim indefinite because it is unclear whether this limitation indicates that other metabolites are also increased in the seed, or whether the limitation indicates that the sulfurous protein content is also increased in other plant parts.

17. Claims 96 and 99 recite the limitation "genetic construct". There is insufficient antecedent basis in claims 12 for this limitation in claims 96 and 99.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-16, 20-23, 28-31, 33-40, 42-44, 47-50, 52-65, 67-69, 83-85, 88-97, and 99-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Molvig et al. (August 1997, Proc. Natl. Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicant's IDS).

20. The claims are drawn to a method of modifying the content and/or composition of one or more metabolites in the storage organ of a plant by expressing a chimeric gene that encodes a sulfur-rich protein, wherein the storage organ is a seed, wherein the sulfur-rich protein is sunflower seed albumin, wherein the sulfur-rich protein is a 2S protein, wherein the plant is a lupin plant, wherein the promoter is the pea vicilin gene promoter, and wherein the transcription terminator is the pea vicilin transcription terminator. The claims are also drawn to a transformed

plant, progeny, or plant part that comprises at least one copy of the chimeric gene in an expressible format, and to the use of the transformed plant, progeny, or plant part to produce a food composition for consumption by animals.

21. Molvig et al. teach a method of modifying the content and/or composition of one or more metabolites in the storage organ of a plant by expressing a chimeric gene that encodes a sulfur-rich protein, wherein the storage organ is a seed, wherein the sulfur-rich protein is sunflower seed albumin, wherein the sulfur-rich protein is a 2S protein, wherein the plant is a lupin plant, wherein the promoter is the pea vicilin gene promoter, and wherein the transcription terminator is the pea vicilin transcription terminator (page 8393, column 2, fourth full paragraph through page 8394). Molvig et al. also teach a transformed plant, progeny, or plant part that comprises at least one copy of the chimeric gene in an expressible format, and the use of the transformed plant, progeny, or plant part to produce a food composition for consumption by animals (page 8395, column 1, paragraph 1; page 8396, column 1, first full paragraph).

22. Although Molvig et al do not directly teach modifying the content and/or composition of fatty acids, starch, fibre, or endogenous anti-nutritional factors of seeds, these features of the claimed invention must be inherently present because practicing the claimed invention does not require additional method steps or the use of additional method components to achieve the desired effect. Additionally, to account for an unexpected increase in the palatability of transgenic seed, Molvig et al. teach that the expression of a chimeric gene that encodes a sulfur-rich protein may alter the synthesis of key catalytic or other regulatory proteins involved in other metabolic pathways, leading to other changes in seed components (page 8397, column 2, first full paragraph).

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23. Accordingly, claims 1-16, 20-23, 28-31, 33-40, 42-44, 47-50, 52-65, 67-69, 83-85, 88-97, and 99-100 are anticipated by Molvig et al.

24. Claims 1-11, 13-14, 20, 65, 67-69, and 83-85 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/27068 (12 October 1995, Applicant's IDS).

25. The claims are drawn to a method of modifying the content and/or composition of one or more metabolites in the storage organ of a plant by expressing a chimeric gene that encodes a sulfur-rich protein, wherein the storage organ is a seed, wherein the metabolite is an endogenous anti-nutritional factor that is a trypsin inhibitor or a chymotrypsin inhibitor, wherein the sulfur-rich protein is rich in methionine, wherein the sulfur-rich protein is a 2S protein, and wherein the plant is a dicotyledonous plant. The claims are also drawn to a transformed plant, progeny, or plant part that comprises at least one copy of the chimeric gene in an expressible format, and to the use of the transformed plant, progeny, or plant part to produce a food composition for consumption.

26. WO 95/27068 teaches a method of modifying the content and/or composition of one or more metabolites in the storage organ of a plant by expressing a chimeric gene that encodes a sulfur-rich protein, wherein the storage organ is a seed, wherein the metabolite is an endogenous anti-nutritional factor that is a trypsin inhibitor or a chymotrypsin inhibitor, wherein the sulfur-rich protein is rich in methionine, wherein the sulfur-rich protein is a 2S protein, and wherein the plant is a dicotyledonous plant (page 12 line 30 through page 17 line 32; pages 19-20 *Tables 1 and 2*; page 26 *Table 6*). WO 95/27068 also teaches a transformed plant that comprises at least one copy of the chimeric gene in an expressible format and the use of the transformed plant,

progeny, or plant part to produce a food composition for consumption. (page 7 lines 15-16; page 16 line 22 through page 17 line 24).

27. Although WO 95/27068 does not directly teach modifying the content and/or composition of fatty acids, starch, or fibre of seeds, these features of the claimed invention must be inherently present because practicing the claimed invention does not require additional method steps or the use of additional method components to achieve the desired effect.

28. Accordingly, claims 1-11, 13-14, 20, 65, 67-69, and 83-85 are anticipated by WO 95/27068.

Claim Rejections - 35 USC § 103

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. Claims 1-65, 67-69, and 83-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Molvig et al. (August 1997, Proc. Natl. Acad. Sci. USA, Vol. 94, pages 8393-8398, Applicant's IDS).

31. The claims are drawn to a method of modifying the content and/or composition of one or more metabolites in the storage organ of a plant by expressing a chimeric gene that encodes a sulfur-rich protein. The claims are also drawn to a transformed plant, progeny, or plant part that comprises at least one copy of the chimeric gene in an expressible format, and to the use of the transformed plant, progeny, or plant part to produce a food composition for consumption by animals.

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32. The teachings of Molvig et al. are discussed *supra*.

33. Molvig et al. do not teach the use of pea or chickpea plants, the use of monocotyledonous plants such as rice, the use of the *Triticum aestivum* HMW glutenin promoter and the NOS transcription terminator, or the modification of the content and/or composition of one or more metabolites in a tuber or a specialised stem.

34. It would have been obvious to one skilled in the art at the time the invention was made to substitute the pea, chickpea, or rice plants of the instant invention for the lupine plant as taught by Molvig et al., given that transformation methods for these plants were known in the art, and given that these plants are commonly used to produce a food composition for consumption. It also would have been obvious to use the *Triticum aestivum* HMW glutenin promoter and the NOS transcription terminator of the instant invention for the transformation of monocotyledonous plants, rather than the pea vicilin gene promoter and the pea vicilin gene transcription terminator as taught by Molvig et al., given that these particular sequences are known to be functional in monocotyledonous plants. Additionally, it would have been obvious to modify the content and/or composition of one or more metabolites in storage organs such as a tuber or a specialised stem as taught in the instant invention, rather than in seeds as taught by Molvig et al., given that tubers and specialised stems are commonly used parts from which a food composition for consumption may be produced.

35. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
June 18, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600

Ef m'Elwain